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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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[REDACTED] EXAMINER

SWARTZ, RODNEY P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1645 | |

DATE MAILED: 08/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/049,753 | CLASS ET AL. | |
| | Examiner Rodney P. Swartz, Ph.D. | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27May2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 38-84 is/are pending in the application.
- 4a) Of the above claim(s) 59-75 and 81-84 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 38-43,45-49,57,58 and 76-80 is/are rejected.
- 7) Claim(s) 44 and 50-56 is/are objected to.
- 8) Claim(s) 38-84 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. . | 6) <input type="checkbox"/> Other: _____ . |

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DETAILED ACTION

1. Applicants' Response to Restriction, received 27May2003, paper#8, is acknowledged.

Applicants elect, with traverse, Invention I, claims 38-58, drawn to H1 histone preparations, and Invention V, claims 76-80, drawn to a method of use of histone for coating devices.

Applicant's election with traverse of in Paper No. is acknowledged. The traversal is on the ground(s) that all claims depend directly or indirectly from independent claim 1 and relate to various uses of a eukaryotic histone H1 protein. Therefore, each of the separate methods relate to a single general inventive concept, i.e., the histone H1 protein. This is not found persuasive because of the reasons put forth in the original restriction, i.e., that each of the methods of Groups II-VIII are drawn to different methods steps with different outcomes..

The requirement is still deemed proper and is therefore made FINAL.

Claims 59-75 and 81-84 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

2. Claims 38-58 and 76-80 are under consideration.

Specification

3. The disclosure is objected to because of the following informalities: It is unclear which references are being referred to on page 30, in examples 2 and 3.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 40 recites “protein is derivated with polyethylene glycol”. It is unclear what are the metes and bounds of “derivated”.

7. Claims 76-80 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: 1) steps by which the composition of claim 38 is attached to the surface of the device or wrap, and 2) the coupling group utilized.

8. Claims 46-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims are drawn to a kit with instructional material which describes use of the composition to inhibit growth of a microorganism. However, it is unclear what are the methods steps of the instructional material.

9. Claims 57 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a wrap comprising the composition of claim 38, and ≥ 1 synthetic polymer and a polymer containing a biological macromolecule. It is unclear what are the metes and bounds, or identity of “biological macromolecule”.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 38, 39, 41, 42, 45, 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Zeppezauer et al (U.S. Pat. No. 5,182,257).

Claims 38, 39, and 49 are drawn to a composition comprising only one listed constituent, i.e., a eukaryotic histone H1 protein.

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Claim 45 is drawn to the composition of claim 38 further comprising a pharmaceutically acceptable carrier.

Zeppezauer et al teach a composition which comprises only one listed constituent, i.e., pure histone H1 and a physiologically acceptable carrier (Claim 6; Col. 7, lines 41-60).

12. Claims 38, 39, 41, 42, 43, 45, are rejected under 35 U.S.C. 102(b) as being anticipated by Zeppezauer et al (U.S. Pat. No. 5,578,571).

Claims 38, 39, and 49 are drawn to a composition comprising only one listed constituent, i.e., a eukaryotic histone H1 protein.

Claims 41 and 42 are drawn to a composition comprising pure histone H1 and either histone H2A, H2B, H3, H4, or H5.

Claim 45 is drawn to the composition of claim 38 further comprising a pharmaceutically acceptable carrier.

Zeppezauer et al teach a composition which comprises \geq H1, H2A, H2b, and a therapeutically acceptable carrier (claim 1).

Claim Objections

13. Claims 44, 50-56 are objected to because they depend from rejected claims. Appropriate correction is required.

Conclusion

14. Claims 38-43, 45-49, 57, 58 and 76-80 are rejected. Claims 44, 50-56 are objected to.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.


RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

August 11, 2003